

UNITED STATES PATENT AND TRADEMARK OFFICE

GARLICK, HARRISON & MARKISON, LLP

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	DATE REC'D	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,188	04/25/2001	12-23-03	John Warrington	054270-0134	3652

34399 7590 12/19/2003

GARLICK HARRISON & MARKISON LLP  
P.O. BOX 160727  
AUSTIN, TX 78716-0727

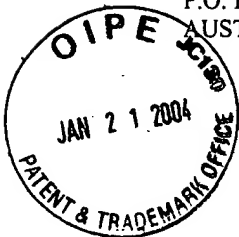
EXAMINER
----------

SHANNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
----------	--------------

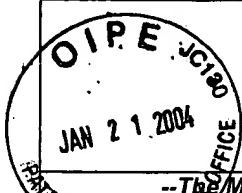
1645

DATE MAILED: 12/19/2003



Please find below and/or attached an Office communication concerning this application or proceed to the next step.

RECEIVED  
JAN 30 2004  
TECH CENTER 1600/2900



## Advisory Action

Application No.

09/841,188

Applicant(s)

WARMINGTON ET AL.

Examiner

Khatol S Shahn-Shah

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

### PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 112 second paragraph.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 18-37.

Claim(s) withdrawn from consideration: None.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

***Attachment to Advisory Action***

1. Applicant's amendment and Reply to a final office action under 37 CFR 1.116, received 11/3/2003 is acknowledged. Claims 1-17 were canceled. Claims 23-30 and 37 have been amended.
2. Claims 18-37 are pending in the application.
3. Affidavit of Professor John Warmington dated September 9, 2003 is acknowledged.
4. On 12/10/2003 applicants' representative Allison Sheiner called in regard to a letter of revocation of power of attorney dated 10/16/2003, which was included in this application by error. The examiner respectfully apologizes for this oversight by the USPTO. The examiner has notified the responsible parties in this office. The document has been removed from this application and has been scanned into the correct application.

***Rejections Withdrawn***

5. Rejection of claims 24-29 and 37 under 35 U.S.C. 112 second- paragraph made in paragraph 13 of the office action mailed July 09, 2003 (paper number 14) is withdrawn in view of the applicant's amendments.

***Rejections Maintained***

6. Rejections of claims 18-34 and under 35 U.S.C. 102(b) as being anticipated by Buckley et al. (US 4,806,465) made in paragraphs 14 and 15 of the office action mailed July 09, 2003 (paper number 14) are maintained.

Applicants' arguments filed 11/03/2003 have been fully considered but they are not persuasive.

Applicants argue that:

- 1) Applicants have argued through an affidavit determined that there is no reactivity between Buckley's antibodies and the claimed antigen preparation when measured via immunoblotting or ELISA.
- 2) Buckley reference describes antigens extracted from the mycelial form of *Candida*, whereas applicants' recited antigens prepared from the blastospore form.
- 3) Molecular weights of disclosed antigens are different.

It is the examiners position that:

In response to the issue (1) The applicants' affidavit has been entered and considered but does not overcome the rejection because the applicants try to argue a reference which is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

In response to the issue (2) Buckley reference describes antigens extracted from both the mycelia or yeast form of *Candida* (see column 4, lines 21-25).

In response to the issue (3) Buckley reference teach multiple antigens including the ones having molecular weights of 55 kDa (see figures 6 and 7) 30 kDa (figure 3) and 20 kDa (see figure 3).

7. Rejection of claims 35-36 and under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 4,806,465) in view of Miyada et al. (US 5,766,874) made in paragraph 16 of the office action mailed July 09, 2003 (paper number 14) is maintained.

Applicants have not argued this rejection.

*Conclusion*

8. Claims 18-37 stand rejected.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.




Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

December 14, 2003



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

**NOTICE OF OFFICE PLAN TO CEASE SUPPLYING COPIES OF CITED U.S. PATENT  
REFERENCES WITH OFFICE ACTIONS, AND PILOT TO EVALUATE THE  
ALTERNATIVE OF PROVIDING ELECTRONIC ACCESS TO SUCH U.S. PATENT  
REFERENCES**

**Summary**

The United States Patent and Trademark Office (Office or USPTO) plans in the near future to: (1) cease mailing copies of U.S. patents and U.S. patent application publications (US patent references) with Office actions except for citations made during the international stage of an international application under the Patent Cooperation Treaty and those made during reexamination proceedings; and (2) provide electronic access to, with convenient downloading capability of, the US patent references cited in an Office action via the Office's private Patent Application Information Retrieval (PAIR) system which has a new feature called "E-Patent Reference." Before ceasing to provide copies of U.S. patent references with Office actions, the Office shall test the feasibility of the E-Patent Reference feature by conducting a two-month pilot project starting with Office actions mailed after December 1, 2003. The Office shall evaluate the pilot project and publish the results in a notice which will be posted on the Office's web site ([www.USPTO.gov](http://www.USPTO.gov)) and in the Patent Official Gazette (O.G.). In order to use the new E-Patent Reference feature during the pilot period, or when the Office ceases to send copies of U.S. patent references with Office actions, the applicant must: (1) obtain a digital certificate from the Office; (2) obtain a customer number from the Office, and (3) properly associate applications with the customer number. The pilot project does not involve or affect the current Office practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of references will continue to be provided by the USPTO for searches and written opinions prepared by the USPTO for international applications during the international stage and for reexamination proceedings.

**Description of Pilot Project to Provide Electronic Access to Cited U.S. Patent References**

On December 1, 2003, the Office will make available a new feature, E-Patent Reference, in the Office's private PAIR system, to allow more convenient downloading of U.S. patents and U.S. patent application publications. The new feature will allow an authorized user of private PAIR to download some or all of the U.S. patents and U.S. patent application publications cited by an examiner on form PTO-892 in Office actions, as well as U.S. patents and U.S. patent application publications submitted by applicants on form PTO/SB08 (1449) as part of an IDS. The retrieval of some or all of the documents may be performed in one downloading step with the documents encoded as Adobe Portable Document format (.pdf) files, which is an improvement over the current page-by-page retrieval capability from other USPTO systems.

## **Steps to Use the New E-Patent Reference Feature During the Pilot Project and Thereafter**

Access to private PAIR is required to utilize E-Patent Reference. If you don't already have access to private PAIR, the Office urges practitioners, and applicants not represented by a practitioner, to take advantage of the transition period to obtain a no-cost USPTO Public Key Infrastructure (PKI) digital certificate, obtain a USPTO customer number, associate all of their pending and new application filings with their customer number, install no-cost software (supplied by the Office) required to access private PAIR and E-Patent Reference feature, and make appropriate arrangements for Internet access. The full instructions for obtaining a PKI digital certificate are available at the Office's Electronic Business Center (EBC) web page at: <http://www.uspto.gov/ebc/downloads.html>. Note that a notarized signature will be required to obtain a digital certificate.

To get a Customer Number, download and complete the Customer Number Request form, PTO-SB125, at: <http://www.uspto.gov/web/forms/sb0125.pdf>. The completed form can then be transmitted by facsimile to the Electronic Business Center at (703) 308-2840, or mailed to the address on the form. If you are a registered attorney or patent agent, then your registration number must be associated with your customer number. This is accomplished by adding your registration number to the Customer Number Request form. A description of associating a customer number with an application is described at the EBC web page at: [http://www.uspto.gov/ebc/registration\\_pair.html](http://www.uspto.gov/ebc/registration_pair.html).

The E-Patent Reference feature will be accessed using a new button on the private PAIR screen. Ordinarily all of the cited U.S. patent and U.S. patent application publication references will be available over the Internet using the Office's new E-Patent Reference feature. The size of the references to be downloaded will be displayed by E-Patent Reference so the download time can be estimated. Applicants and registered practitioners can select to download all of the references or any combination of cited references. Selected references will be downloaded as complete documents as Adobe Portable Document Format (.pdf) files. For a limited period of time, the USPTO will include a copy of this notice with Office actions to encourage applicants to use this new feature and, if needed, to take the steps outlined above in order to be able to utilize this new feature during the pilot and thereafter.

During the two-month pilot, the Office will evaluate the stability and capacity of the E-Patent Reference feature to reliably provide electronic access to cited U.S. patent and U.S. patent application publication references. While copies of U.S. patent and U.S. patent application publication references cited by examiners will continue to be mailed with Office actions during the pilot project, applicants are encouraged to use the private PAIR and the E-Patent Reference feature to electronically access and download cited U.S. patent and U.S. patent application publication references so the Office will be able to objectively evaluate its performance. The public is encouraged to submit comments to the Office on the usability and performance of the E-Patent Reference feature during the pilot. Further, during the pilot period registered practitioners, and applicants not represented by a practitioner, are encouraged to experiment with the feature, develop a proficiency in using the feature, and establish new internal processes for using the new access to the cited U.S. patents and U.S. patent application publications to prepare for the anticipated cessation of the current Office practice of supplying copies of such cited

references. The Office plans to continue to provide access to the E-Patent Reference feature during its evaluation of the pilot.

### **Comments**

Comments concerning the E-Patent Reference feature should be in writing and directed to the Electronic Business Center (EBC) at the USPTO by electronic mail at [eReference@uspto.gov](mailto:eReference@uspto.gov) or by facsimile to (703) 308-2840. Comments will be posted and made available for public inspection. To ensure that comments are considered in the evaluation of the pilot project, comments should be submitted in writing by January 15, 2004.

Comments with respect to specific applications should be sent to the Technology Centers' customer service centers. Comments concerning digital certificates, customer numbers, and associating customer numbers with applications should be sent to the Electronic Business Center (EBC) at the USPTO by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

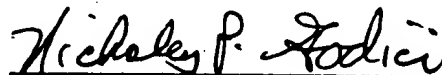
### **Implementation after Pilot**

After the pilot, its evaluation, and publication of a subsequent notice as indicated above, the Office expects to implement its plan to cease mailing paper copies of U.S. patent references cited during examination of non provisional applications on or after February 2, 2004; although copies of cited foreign patent documents, as well as non-patent literature, will still be mailed to the applicant until such time as substantially all applications have been scanned into IFW.

### **For Further Information Contact**

Technical information on the operation of the IFW system can be found on the USPTO website at <http://www.uspto.gov/web/patents/ifw/index.html>. Comments concerning the E-Patent Reference feature and questions concerning the operation of the PAIR system should be directed to the EBC at the USPTO at (866) 217-9197. The EBC may also be contacted by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

Date: 12/1/03



Nicholas P. Godici  
Commissioner for Patents